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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/424,080	02/14/2000	VLADIMIR ZAVIALOV	933-149PCT	7527

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EXAMINER

SCHWADRON, RONALD B

ART UNIT PAPER NUMBER

1644

DATE MAILED: 05/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/424,080

Applicant(s)

ZAVIALOV ET AL.

Examiner

Ron Schwadron, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4,5 and 19 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1,4,5,19 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

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1. Applicant's election with traverse of the species SEQ. ID. No 1 in the reply filed on 3/9/2005 is acknowledged. The traversal is on the ground(s) that are stated in said response. This is not found persuasive because of the following reasons. The species elucidated in the previous Office Action are distinct because they have different sequences. It would require an undue burden to search further sequences. It is also noted that the MPEP section 811.02 states:

811.02 Even After Compliance With Preceding Requirement

Since 37 CFR 1.142(a) provides that restriction is proper at any stage of prosecution up to final action, a second requirement may be made when it becomes proper, even though there was a prior requirement with which applicant complied. Ex parte Benke, 1904 C.D. 63, 108 O.G. 1588 (Comm'r Pat. 1904).

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 1,4,5,19 are under consideration.

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. The rejection of Claims 1,3-5 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for the reasons enunciated in the pervious Office Action, paragraph 4, is withdrawn in view of the amended claims, applicants arguments and the cancellation of claim 3.

5. The rejection of claim 1 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the reasons

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elaborated in the previous Office action, paragraph 5, is withdrawn in view of the amended claim.

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claim 1,19 stand rejected under 35 U.S.C. 102(b) as being anticipated by Gryn et al. for the reasons elaborated in the previous Office action. Applicants arguments have been considered and deemed not persuasive.

Gryn et al. teach a composition of cyclosporin and interferon alpha (see page 222, second column, wherein the composition is the aforementioned agents in their respective containers). Original claim 5 in priority document FI 972121 indicates that the term composition as used by applicant encompasses physically separated preparations of the peptide and immunosuppressant. The peptide recited in the claims is found in interferon alpha. The functional properties recited in the claim are inherent properties of the aforementioned composition.

Regarding applicants comments, original claim 5 in priority document FI 972121 indicates that the term **composition as used by applicant** encompasses physically separated preparations of the immunosuppressant and peptide. The MPEP section 2111.01 discloses that:

III. < APPLICANT MAY BE OWN LEXICOGRAPHER

***> An applicant is entitled to be his or her own lexicographer and may rebut the presumption that claim terms are to be given their ordinary and customary meaning by clearly setting forth a definition of the term that is different from its ordinary and customary meaning(s). See In re Paulsen, 30 F.3d 1475, 1480, 31 USPQ2d 1671, 1674 (Fed. Cir. 1994) (inventor may define specific terms used to describe invention, but must do so "with reasonable clarity, deliberateness, and precision" and, if done, must "set out his uncommon definition in some manner within the patent disclosure" so*

as to give one of ordinary skill in the art notice of the change" in meaning) (quoting Intellicall, Inc. v. Phonometrics, Inc., 952 F.2d 1384, 1387-88, 21 USPQ2d 1383, 1386 (Fed. Cir. 1992)). Where an explicit definition is provided by the applicant for a term, that definition will control interpretation of the term as it is used in the claim. Toro Co. v. White Consolidated Industries Inc., 199 F.3d 1295, 1301, 53 USPQ2d 1065, 1069 (Fed. Cir. 1999) (meaning of words used in a claim is not construed in a "lexicographic vacuum, but in the context of the specification and drawings"). Any special meaning assigned to a term "must be sufficiently clear in the specification that any departure from common usage would be so understood by a person of experience in the field of the invention." Multiform Desiccants Inc. v. Medzam Ltd., 133 F.3d 1473, 1477, 45 USPQ2d 1429, 1432 (Fed. Cir. 1998). See also Process Control Corp. v. HydReclaim Corp., 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999) and MPEP § 2173.05(a).

In the instant case, the term composition as referred to in original claim 5 in priority document FI 972121 indicates that the term **composition as used by applicant** encompasses physically separated preparations. Applicants comments also involve limitations not currently recited in the claims (eg. that the agents are administered at the same time), wherein the claims currently recite nothing more than a composition comprising two agents. Original claim 5 in priority document FI 972121 indicates that the term composition as used by applicant encompasses physically separated preparations of the immunosuppressant and peptide wherein the two components are used separately (which would encompass administration of the two components at different times). Regarding applicants comments about peptide versus protein, the "peptide comprises" recited in the claim encompasses use of intact interferon alpha. There is no definition of said phrase in the specification to the contrary. Regarding the specification, page 5, said passage of the specification does not indicate that "peptide comprises" excludes full length protein.

8. The rejection of claim 1 stands rejected under 35 U.S.C. 102(b) as being anticipated by Yoshida et al. for the reasons elaborated in the previous Office action is withdrawn in view of the amended claim which no longer encompasses interferon beta.

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9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 1, 5, 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gryn et al. in view of Zav'Yalov et al. (Molecular Immunology 1995; 32(6): 425-431; IDS document) and Fish (WO 94/01457).

Gryn et al. teach a composition of cyclosporin and interferon alpha (see page 222, second column, wherein the composition is the aforementioned agents in their respective containers). The peptide recited in the claims is found in interferon alpha. The functional properties recited in the claim are found in the aforementioned composition because the aforementioned composition is the same as the composition recited in the claims. Gryn et al. do not teach SEQ ID NO: 1 (also known as alpha-peptoferron). Zav'Yalov et al. teach a bioactive peptide comprising positions 130-137 (i.e. an 8-mer) of interferon-alpha2 (authors definition: alpha-peptoferron) which is a bioactive peptide and displaces labeled IFN-alpha2 from the IFN-alpha2/receptor complex, meaning that it interacts with the high-affinity binding site of IFN-alpha2 (see the abstract and page 425, left column, and page 427, right column in particular). Fish teaches that interferon alpha derived peptides which bind the receptor for interferon

alpha can be used in pharmaceutical compositions (see page 2). One of the peptides disclosed by Fish is a 11mer which contains the peptide of SEQ. ID. No:1. It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Gryn et al. teach a composition of cyclosporin and interferon alpha whilst Zav'Yalov et al. teach a bioactive interferon-alpha2 derived peptide which interacts with the high-affinity binding site of IFN-alpha2 and Fish teaches that interferon alpha derived peptides which bind the receptor for interferon alpha can be used in pharmaceutical compositions. One of ordinary skill in the art would have been motivated to do the aforementioned because Fish teaches that interferon alpha derived peptides which bind the receptor for interferon alpha can be used in pharmaceutical compositions and Zav'Yalov et al. teach that loop DE (AKA alpha peptoferin) mediates immunomodulatory activity of interferon alpha (see last sentence, page 428, second column, continued on next page).

Applicants arguments are as addressed in paragraph 6 of this Office Action.

11. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gryn et al. in view of Zav'Yalov et al. (Molecular Immunology 1995; 32(6): 425-431; IDS document) and Fish (WO 94/01457) as applied to claims 1, 5, 19 above, and further in view of Isoai et al. (Cancer Research 1994 March; 54: 1264-1270).

The previous rejection renders obvious the claimed invention except wherein the peptide is bound to a small molecular or macromolecular substance to increase the stability of the peptide. Isoai et al. teach a peptide chemically coupled to albumin to form stable entities – and the conjugate was more stable than the peptide alone (see the abstract in particular). Further, albumin was chosen because it is the most abundant and stable protein in serum and would increase the half-life of the peptide (see page 1264, right column, paragraph 3 in particular). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Isoai et al. teach a peptide chemically coupled to albumin to form stable entities – and the conjugate was more stable than the

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peptide alone. One of ordinary skill in the art would have been motivated to do this because the stability of the peptide was greater when conjugated to albumin as taught by Isoai et al.

Applicants arguments are as addressed in paragraph 6 of this Office Action.

12. No claim is allowed.

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ron Schwadron, Ph.D. whose telephone number is 571 272-0851. The examiner can normally be reached on Monday-Thursday 7:30-6:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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A handwritten signature in black ink, appearing to read 'Ron Schwadron', with a stylized, cursive script.

RONALD B. SCHWADRON
PRIMARY EXAMINER
GROUP 1800 | 600

Ron Schwadron, Ph.D.
Primary Examiner
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